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Dockets Management Branch (HFA-305) 3085 '99 MAY 27 A9:51  
Food and Drug Administration  
5630 Fishers Land Room 1061  
Rockville, Maryland 20857-0003

Re: Docket No. 98N-1265

Food and Drug Administrator:

I am against the FDA's proposed Memorandum of Understanding published 1-21-99. It concerns me that it decreases legitimate and fair competition in medical wisdom, and inappropriately decreases the full range of pharmaceutical choices for U.S. citizens.

U.S. educated consumers of medicines believe in informed consent health care and that the safety of the patient is rightfully paramount, even superceding the marketing successes and special interests of the supermarketers of pharmaceutical products.

Please do not deliver U.S. women as a captive market to the pharmaceutical giants that rely on the crass marketing of patent derivatives to an unsuspecting public. Allow fair competition to permit the parallel presence of non-patentable medicines.

There are botanical compounds which are identical to women's endogenous proteins, and which are non-patentable, and they do safely and very completely serve their medical needs as prescribed by a physician. In a free market such non-patent medicines should continue to remain available for patients by prescription through their accredited physicians and be available through compounding pharmacists.

I believe that the competition is healthy and best serves the public interest. It is not wise to further marginalize compounded medicines that do safely serve the needs of U.S. women. Please do not cater to the drug industry with booster legislation, inoculating against competition, to favor the sales of patented medicines which are derivative products, and are not identical to women's endogenous proteins. I believe there is a conflict of interest in the medical industry informing women their uterii are useless, surgically harvesting them, then marketing back their essential hormones in inferior commercial products, that are non-identical, patent derivatives.

This vehicle delivers a captive market for patent medicines, that relies largely on the false counsel of advertising, the ignorance of women, and the social inhibitions silencing public discussion of these matters. It vastly oversimplifies complex human physiology, and needlessly compromises women's health by subjecting them to the "quick fix", a sanitized future with an overly optimistic picture of the benefits of patent medicines to completely provide for their well being in health.

98N-1265

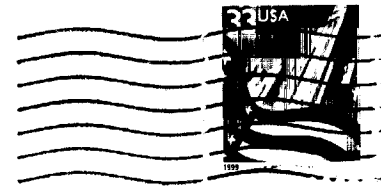
Sincerely,  
Allison Leisten

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